



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

March 10, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: In re Korangy Radiology Associates, P.A., et al.
FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Joint Notice And Agreement To Resolve Discovery Dispute.

If you have any questions, please call me at (301) 827-7138. Thank you.

Sincerely yours,

Douglas A. Terry
Assistant Chief Counsel
for Enforcement

Enclosure

cc w/enc.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz
Thomas M. Jakub, CDRH
Louis J. Kaufman, CDRH
Heyward L. Rourk, CDRH
Michael P. Divine, CDRH
Pamela B. Schweikert, DCMO
Karen Schifter, OCC

2003H-0432

STP1

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)

KORANGY RADIOLOGY ASSOCIATES, P.A.,)
trading as BALTIMORE IMAGING CENTERS,)
a corporation,)

and)

AMILE A. KORANGY, M.D.,)
an individual.)
_____)

ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY

FDA Docket: 2003H-0432

**Joint Notice And Agreement To
Resolve Discovery Dispute**

Respondents, Korangy Radiology Associates, P.A., and Amile A. Korangy, M.D., and Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration (FDA), by their undersigned counsel, file this Joint Notice And Agreement To Resolve Discovery Dispute and agree to the terms contained herein.

Agreement To Resolve Discovery Dispute

On February 13, 2004, Respondents filed "Respondents' First Request for Production of Documents" (Respondents' Document Request). On February 26, 2004, Complainant filed "Complainant's Motion for Protective Order" stating its objections to Respondents' Document Request. On March 9, 2004, counsel for Respondents and Complainant spoke by telephone and discussed Complainant's objections. Respondents and Complainant

agree that Complainant will produce the following documents in response to Respondents' Document Request:

1. Copies of all Warning Letters issued by FDA to any mammography facility for conducting mammography without a valid certificate that has been issued or renewed under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b.

2. Copies of the facility's response, if any, to the Warning Letters described in paragraph 1, subject to applicable redactions to protect privileged, confidential, personal, or private information if necessary.


3. A list of all Warning Letters issued by FDA to mammography facilities for violations of the MQSA and a description of the nature of such violations.

4. In any case in which FDA suspended a facility's certificate to perform mammography, a summary describing the alleged violations leading to such suspension and a description of the disposition or current status of such case.

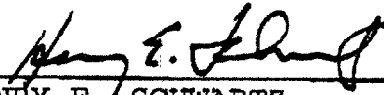
5. Copies of the pleadings in any case in which Complainant has filed an administrative action for civil money penalties against a mammography facility under the MQSA, except that patient records constituting or accompanying such pleadings shall not be produced.

Accordingly, it is unnecessary for the Presiding Officer to rule on Complainant's Motion for Protective Order or to take any other action at this time.

Respectfully submitted,



DOUGLAS A. TERRY
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(301) 827-7138




HENRY E. SCHWARTZ
Henry E. Schwartz LLC
Attorney for Respondents
901 Dulaney Valley Road, Suite 400
Towson, MD 21204
(410) 938-8703

CERTIFICATE OF SERVICE

I hereby certify that, on this tenth day of March, 2004, I have caused a copy of the foregoing Joint Notice And Agreement To Resolve Discovery Dispute to be served by Federal Express overnight delivery on:

Henry E. Schwartz
Henry E. Schwartz LLC
Attorney for Respondents
901 Dulaney Valley Road, Suite 400
Towson, MD 21204



DOUGLAS A. TERRY
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